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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,395	09/01/2004	Tung M Fong	21041P	2821

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EXAMINER	
PAK, MICHAEL D	

ART UNIT	PAPER NUMBER
1646	

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01/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,395	FONG ET AL.	
	Examiner	Art Unit	
	Michael Pak	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14, 25-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Amendment filed on October 26, 2007 has been entered.

2. Applicant's arguments filed October 26, 2006, have been fully considered but they are not found persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-14 and 25-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 1-14 and 25-27 encompass a method of treating obesity by administering a compound that antagonizes CB1 receptor, inhibits 11β-HSD1 and has ion channel activity. Claim 28 encompass a method of preventing obesity by administering a compound that antagonizes CB1 receptor, inhibits 11β-HSD1 and has ion channel activity. However, the essential feature of the invention is not clear because the

specification does not disclose a compound which treats or prevents obesity by administering a compound that antagonizes CB1 receptor, inhibits 11β-HSD1 and has ion channel activity. One of skilled in the art cannot envision the full genus of molecules of the claimed compound with the activity and treats or prevents obesity. The claims encompass variants whose structure is not known or other variants with different function from compounds taught in the specification. Claimed variants encompass a large genus of molecules which are variants whose function has yet to be identified. *University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification.

Applicants argue that IC50 of greater than 2 uM in the ion channel assay is desirable. However, the claims do not recite the term IC50 and the term 2 uM alone does not convey that concept.

Furthermore, it should be noted that the reference to pages 33-34 do not provide the data for a single molecule which has both CB1 Receptor antagonism and inhibition of 11β-HSD1. The data only provide molecules which acts on one but not both.

4. Claims 1-14 and 25-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating obesity using a compound which antagonizes cannbinoid receptor with specific structure and function, does not reasonably provide enablement for a method of of treating obesity using a compound that antagonizes CB1 receptor, inhibits 11β-HSD1 and has ion channel

activity nor a method of preventing obesity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The first paragraph of § 112 requires that the patent specification enable "those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" Genentech, Inc. v. Novo Nordisk AIS, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)); see also In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). ("[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art."). Whether making and using the invention would have required undue experimentation, and thus whether the disclosure is enabling is a legal conclusion based upon several underlying factual inquiries. See In re Wands, 858 F.2d 731, 735, 736-37, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir. 1988). As set forth in Wands, the factors to be considered in determining whether a claimed invention is enabled throughout its scope without undue experimentation include the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Likewise, in Amgen Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991), the court affirmed the holding of invalidity of claims to analogs of the

EPO gene under § 112 for lack of enablement where applicants had claimed every possible analog of the EPO gene but had disclosed only how to make EPO and a very few analogs. "[D]espite extensive statements in the specification concerning all analogs of the EPO gene that can be made, there is little enabling disclosure of the particular analogs and how to make them .... There may be many other genetic sequences that code for EPO-type products. Amgen has told how to make and use only a few of them and is therefore not entitled to claim all of them." Id., 927 F.2d at 1213-14, 18 USPQ2d at 1027.

Claims 1-14 and 25-27 encompass a method of treating obesity by administering a compound that antagonizes CB1 receptor, inhibits 11β-HSD1 and has ion channel activity. Claim 28 encompass a method of preventing obesity by administering a compound that antagonizes CB1 receptor, inhibits 11β-HSD1 and has ion channel activity. However, the specification does not teach a method of treating obesity with a compound which treats or prevents obesity by administering a compound that antagonizes CB1 receptor, inhibits 11β-HSD1 and has ion channel activity because the specification does not teach a compound with all the activity nor a method of preventing obesity. The state of the art is such that one skilled in the art prior to the time of the invention used specific compounds with known structure to treat obesity with antagonists of cannbinoid receptors (Finke et al., WO 03/007887 A2). The amount of direction provided in the specification is limited to a specific species of compounds with specific structure which are used in in vitro assays of cannabinoid receptors, enzyme assays or ion channel activity. However, the specification does not disclose a single

compound which works in all the in vitro assays nor examples of administration of the compound to treat or prevent obesity. One skilled in the art would require empirical experimentation in order to determine the specific compounds which have all the claimed activity or prevent obesity. However, the specification nor the state of the art does not teach how to prevent obesity. Thus, one skilled in the art cannot use the primary amino acid sequence of the different polypeptides of receptors, enzymes and ion channels alone to predict the tertiary structure of which will all interact with the compound. No working example is provided to determine whether a change in the domains of any one polypeptide fragment or variant would provide proper function. It would require empirical experimentation to determine whether the variants compounds would be functional as claimed in all three types of proteins. Thus, the claimed variants encompass a genus with a large number of species which are not functional. In view of the extent and the unpredictability of the experimentation required to practice the invention as claimed, one skilled in the art could not make the invention without undue experimentation.

Therefore, based on the above Wands analysis, a preponderance of the evidence supports a conclusion that one skilled in the art would not have been enabled to make and use the claimed invention without undue experimentation.
Applicants argue that it is routine to confirm that these disclosed compounds have or don have ion channel activity. However, the claims do not recite the term IC50 and the term 2 uM alone does not convey that concept.

Furthermore, it should be noted that data on pages 33-34 do not provide the data for a single molecule which has both CB1 Receptor antagonism and inhibition of 11β-HSD1. The data only provide molecules which acts on one but not both. One skilled in the art was not aware of the compound including the working example species where a single molecule which has both CB1 Receptor antagonism and inhibition of 11β-HSD1. It would require undue experimentation to determine a molecule with both activities since the molecules which act on individual CB1 or 11β-HSD1 are quite different from each other and thus could not extrapolate to binding to both.

5. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached on 8:00 - 2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael D. Pak

Michael Pak
Primary Patent Examiner
Art Unit 1646
17 January 2008